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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/341,821 | 09/01/1999 | MICHAEL J. WARING | CV0244 | 5635 |

7590

12/08/2003

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| EXAMINER |
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GHALI, ISIS A D

| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/08/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/341,821 | Applicant(s) WARING ET AL. | |
| | Examiner Isis Ghali | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,13-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,13-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' request Under 1.114, filed 09/26/2003.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/26/2003 has been entered.

Claims 1-6, 8-10, 13-15, 17-20 are pending in the application.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

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- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,976,223 ('223).

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The instant claim 1 reads on an aerosol container containing gel. Instant claim 13 reads on treating wound by discharging onto the wound a gel from an aerosol container. The dependent claims 2-4 and 17 recite the gel comprising hydrocolloid (claims 2 and 17), gelling agent (claim 3) and glycol (claim 4).

US '223 disclosed an aerosol container containing gel, which reads on claim 1, and comprising carboxymethyl cellulose, gelling agent and alginate, which reads on claims 2, 3 and 17. The gel comprises polyethylene glycol, which reads on claim 4 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reads on claim 13 (col.9, lines 20-55). The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

The limitations of claims 1-4, 13 and 17 are met by US '223.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5, 6, 10, 14, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '223 in view of EP 666 081 ('081).

The teaching of US '223 are disclosed under 102 rejection above.

US '223 does not teach the same composition of the gel as claimed in claim 5. The reference does not teach the gel is sterile as claimed in claims 6, 10 and 15 or the viscosity of the gel as claimed in claim 18. The reference does not teach the wound to be treated is a sinus wound as claimed in claim 14.

No superior and unexpected results of record to show the criticality in treating of sinus wound using the instant composition.

EP '081 teaches gel wound dressing comprising material comprising:

- a) from about 0.05% to 10% by weight of natural gelling agent;
- b) from about 1.0% to 10% by weight of hydrocolloid;

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c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

The above ingredients read on claim 5. The wound dressing is packaged and sterilized, which reads on claims 6, 10 and 15. The gel composition of the reference can be extruded in the form of gel through a nozzle (page 2, lines 20-24; page 3, lines 14-18).

The gel of the reference has viscosity of 50-800 Pas, which reads on claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating sinus wound (page 2, lines 8-9).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an aerosol containing gel wound dressing as disclosed by US '223, and replace the gel by the sterile gel composition disclosed by EP '081, motivated by the teaching of EP '081 that the gel composition has a viscosity that reduces the flow of the gel from the wound site and conforms readily to the shape of the wound particularly when the wound includes a cavity, with reasonable expectation of the delivered aerosol containing gel to treat wounds, and in particular sinus wounds with success.

7. Claims 8, 9, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,059,187 ('187) in view of US '223.

US '187 teaches a method for providing an aerosol container and method for cleaning the wound including the steps of introducing the wound cleaning material

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though an opening into a pouch and then the opening is closed by a valve, the container is then sterilized and the propellant is introduced into the can (abstract; col.3, lines 1-10; col.5, lines 8-21).

US '187 does not teach the aerosol vessel containing gel.

The teachings of US '223 are discussed under 102 rejection above, an aerosol containing wound treating gel.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to provide an aerosol for wound treating produced by the method disclosed by US '187, and replace its contents by wound-treating gel as disclosed by US '223, motivated by the teaching of US '223 that gel provides a soothing strippable gel bandage that excludes air, with reasonable expectation of the delivered aerosol containing gel to treat wound with success.

Response to Arguments

8. Applicant's arguments with respect to claims 1-6, 8-10, 13-15, 17-20 have been considered but are moot in view of the new ground(s) of rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

**ISIS GHALI
PATENT EXAMINER**